General

Guideline Title

ACR Appropriateness Criteria® vomiting in infants up to 3 months of age.

Bibliographic Source(s)

Raske ME, Dempsey ME, Dillman JR, Dory CE, Garber M, Hayes LL, Iyer RS, Kulkarni AV, Myseros JS, Rice HE, Rigsby CK, Ryan ME, Strouse PJ, Westra SJ, Wootton-Gorges SL, Coley BD, Karmazyn B, Expert Panel on Pediatric Imaging. ACR Appropriateness CriteriaÂ® vomiting in infants up to 3 months of age [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 10 p. [43 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Bulas D, McGrane SL, Coley BD, Karmazyn B, Barr LL, Binkovitz LA, Dory CE, Garber M, Hayes LL, Keller MS, Kulkarni AV, Meyer JS, Milla SS, Myseros JS, Paidas C, Expert Panel on Pediatric Imaging. ACR Appropriateness Criteria® vomiting in infants up to 3 months of age. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 9 p. [58 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Vomiting in Infants Up to 3 Months of Age

Variant 1: Bilious vomiting in neonate up to 1 week old.

Radiologic Procedure	Rating	Comments	RRL*
X-ray abdomen	9	An initial radiograph will help determine further workup strategy.	☢☢
X-ray upper GI series	8		☢☢☢
X-ray contrast enema	7	Consider this procedure when abdominal radiograph suggests distal bowel obstruction.	☢☢☢☢
US abdomen (UGI tract)	4		O

Radiologic Procedure	Rating	Comments	RRL*
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Bilious vomiting in infant 1 week to 3 months old.

Radiologic Procedure	Rating	Comments	RRL*
X-ray upper GI series	9		☢☢☢
X-ray abdomen	5		☢☢
US abdomen (UGI tract)	3		O
Tc-99m sulfur colloid reflux scintigraphy	1		☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Intermittent nonbilious vomiting since birth.

Radiologic Procedure	Rating	Comments	RRL*
X-ray upper GI series	6		☢☢☢
US abdomen (UGI tract)	4		O
Tc-99m sulfur colloid reflux scintigraphy	3	This procedure may seldom provide useful information about gastric emptying and GER.	☢☢☢
X-ray abdomen	1		☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: New onset nonbilious vomiting.

Radiologic Procedure	Rating	Comments	RRL*
US abdomen (UGI tract)	9	In this procedure, particular attention should be paid to gastric pylorus.	O
X-ray upper GI series	6	This procedure is the first choice if technician has limited experience with US of the pylorus and if clinical presentation is atypical for hypertrophic pyloric stenosis.	☢☢☢
X-ray abdomen	2		☢☢
Tc-99m sulfur colloid reflux scintigraphy	1		☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Vomiting, or the forceful extrusion of gastric contents, is never normal in the neonate and usually occurs because of complete or partial obstruction somewhere along the course of the gastrointestinal (GI) tract between the stomach and cecum. Clinically, vomiting is categorized as being nonbilious or bilious; the latter suggests the point of obstruction is distal to the ampulla of Vater. Most commonly, nonbilious "vomiting" is actually regurgitation (gastroesophageal reflux [GER]). The clinical differentiation between vomiting and regurgitation may be challenging.

Regurgitation, or GER, is normal in the first 3 months of life and resolves in time. It usually has no definitive pathologic cause and is unrelated to a functional defect. Rarely, regurgitation may be due to displacement of a portion of the stomach into the chest (i.e., hiatal hernia). In other cases, low esophageal sphincter pressures or delays in gastric emptying have been implicated as causative and typically resolve in time.

Parental complaints of vomiting or regurgitation in neonates during the first 3 months of life are common. The cause is usually GER, particularly in the first weeks of life and with overfeeding. Infants with normal weight gains tend not to have disease as the cause of their vomiting. However, bilious emesis or repeated forceful vomiting should be evaluated for underlying pathologies. When evaluating a neonate who presents in the first week of life with vomiting, a congenital GI tract abnormality is a primary consideration. Upper or lower tract abnormalities can cause vomiting with the possible etiologies including malrotation with or without volvulus, atresia of the antropyloric region, atresia/stenosis of the small bowel or colon, functional obstructions caused by Hirschsprung disease, functional immaturity of the colon, and meconium ileus. Importantly, although malrotation most commonly presents in newborns, it can present at any time during life with decreasing frequency with age.

Several GI pathologies to consider in a vomiting infant outside of the newborn time period include hypertrophic pyloric stenosis (HPS), pylorospasm, formula intolerance, and gastroenteritis. In a young infant, less common GI etiologies include neonatal appendicitis, intussusception, gastric ulcer disease, gastric volvulus, and lactobezoar. Medical causes to consider include sepsis, enteritis, pneumonia, otitis media, meningitis, raised intracranial pressure (from tumor, trauma, or hydrocephalus), kernicterus, metabolic disorders (phenylketonuria, hyperammonemia, maple syrup urine disease, galactosemia, diabetes, adrenocortical hyperplasia, methylmalonic acidemia), diencephalic syndrome, and rarely drugs or toxic agents.

Diagnostic workup should start with a thorough clinical evaluation. History and physical examination can lead to the diagnosis in many instances. Viral gastroenteritis often appears in epidemics, with sudden onset of vomiting, mild fever, diarrhea, and a relatively short duration. Systemic infections and metabolic disorders may be diagnosed by clinical and laboratory criteria. HPS may be diagnosed by feeling the classic "olive" of hypertrophied muscle. Intussusception, which is unusual in the first 3 months of life, may be diagnosed clinically by crampy abdominal pain sometimes progressing to bloody stools. Patients with increased intracranial pressure often have neurologic signs.

When the clinical and laboratory assessment provides a definitive diagnosis and treatment plan, radiologic imaging is not required. Clinical diagnostic uncertainty requires use of imaging.

The imaging workup of vomiting patients in the newborn to 3-month-old age group is discussed with regard to three different clinical scenarios:

1. Bilious vomiting
2. Intermittent nonbilious vomiting since birth
3. New-onset projectile nonbilious vomiting

Discussion of the Imaging Modalities by Variant

Variants 1 and 2: Bilious Vomiting

Regurgitation of the first few feedings of life is not uncommon. These infants must, however, be watched closely and examined frequently. The quality of regurgitated material gives clues as to location of possible obstruction. Bilious vomiting is usually due to sepsis or obstruction. It requires urgent diagnosis and treatment because midgut volvulus about the superior mesenteric artery (SMA) may lead to ischemia and necrosis of the small bowel distal to the point of volvulus. In a study of 45 patients with bilious vomiting in the first 72 hours of life, 20% had midgut volvulus and 11% had a lower GI cause (meconium plug syndrome or left-sided microcolon). Abdominal radiograph can help in choosing the most appropriate fluoroscopy. One must be wary to differentiate true bilious vomiting from inconsequential regurgitation of yellow colostrum or vomitus with meconium which is more indicative of distal bowel obstruction.

Evaluation for Malrotation and Midgut Volvulus

Abdominal Radiographs

Abdominal radiographs have a role in determining subsequent imaging workup, keeping in mind that normal abdominal radiographs do not exclude the diagnosis of malrotation. In one study, only 44% of patients who required surgery for bilious vomiting had definitively positive radiograph

readings. If the radiographs do show signs of obstruction, the pattern of bowel distension helps to define whether the obstruction is proximal or distal, directing further evaluation with an upper GI (UGI) series or contrast enema, respectively.

Contrast Upper Gastrointestinal Series

To answer the key imaging question in such patients - that is, whether the child has a mechanical obstruction - requires direct imaging of the stomach and small bowel. The barium UGI series evaluates the esophagus, stomach, pylorus, and the duodenum to the duodenal jejunal junction, indicating the location of the ligament of Treitz. Although the UGI series is considered the gold standard for evaluating malrotation, false-positive and false-negative interpretations may occur. In a retrospective review of 229 cases, UGI had a sensitivity of 96% with 2 false-positives (abnormal jejunal position with no malrotation) and 7 false-negatives (normal jejunal position with malrotation). Two other studies noted false-positive rates of 10% and 15%, respectively. The studies concluded that redundant duodenum, bowel distension, and jejunal position can lead to inaccurate UGI interpretation, thus meticulous technique is warranted.

Ultrasound

There is overall limited evidence of the accuracy of ultrasound (US) as the primary imaging modality in evaluating malrotation and midgut volvulus. There are 2 anatomical landmarks that can be evaluated by US that may indicate malrotation: position of the superior mesenteric vein (SMV) in relation to the SMA and the position of the third part of the duodenum behind the SMA. A normal SMV/SMA relationship does not preclude malrotation, with both false-positive (21%) and false-negative (2% to 3%) results reported. Obscuration of the SMA and SMV by bowel gas has been reported to occur in up to 17% of cases. In a small prospective series, US demonstrated abnormal position of the duodenum in 50% of children who had surgery for malrotation. In addition, malrotation represents a spectrum of abnormal bowel fixation that may include a situation where the duodenum courses behind the SMA.

It is important to recognize sonographic features of midgut volvulus as they can help to substantiate the diagnosis in an equivocal UGI study or when US is performed for other indications (e.g., evaluation for HPS). US findings in midgut volvulus include duodenal dilation with tapering, fixed midline bowel, whirlpool sign, and dilation of the distal SMV.

X-Ray Contrast Enema

Abnormalities of the lower GI tract that cause bilious vomiting may be demonstrated by barium enema. The use of barium enema for analyzing malrotation is less direct than analysis by UGI series. Approximately 20% of barium enemas may be falsely negative, while up to 15% of infants have a high mobile cecum that may cause false positive interpretations of the study.

Nuclear Medicine

Nuclear medicine studies, which can be highly effective in analyzing gastric emptying and GER, have no significant role in the evaluation of the neonate with acute bilious vomiting.

Variant 3: Intermittent Nonbilious Vomiting Since Birth

There are several common causes of intermittent vomiting since birth. In a review of 145 such cases, 43 were due to idiopathic GER, 40 to HPS, 27 to overfeeding, 15 to pylorospasm, 14 to milk allergy, and one to gastroenteritis. Other diagnostic possibilities include gastric volvulus and, rarely, gastric ulcers.

The most common cause for intermittent vomiting or regurgitation since birth is GER. The brief passage of gastric contents into the esophagus (GER) is a normal physiologic process that occurs in healthy infants and children. Gastroesophageal reflux disease (GERD) occurs when GER causes complications such as poor weight gain or esophagitis. Competence of the lower esophageal sphincter is based on anatomic and physiologic factors that are not perfectly understood. The sphincter mechanism is not fully mature for at least the first 6 weeks of life. This explains the decreased incidence of GER after infancy. There is no consensus on the optimal workup of GER and the significance of a "positive" test.

Evaluation for Gastroesophageal Reflux

Most children with GER who are otherwise healthy do not need any diagnostic workup. In children that have symptoms referable to suspected GER, a diagnostic workup may be undertaken. The current gold standard evaluation is the extended pH probe. UGI series and/or reflux scintigraphy have limited roles in diagnosis of GER and its complications. However, although the UGI is insensitive in detecting reflux, it has an important role to exclude anatomic abnormalities as the cause of the patient's vomiting/regurgitation.

Radiographs

Radiographs do not play a role in the diagnosis of GER.

Contrast Upper Gastrointestinal Series

Clinical practice guidelines on GER from 2001 stated that the sensitivity, specificity, and positive predictive values of UGI series range from 31% to 86%, 21% to 83%, and 80% to 82%, respectively, when compared to esophageal pH monitoring. The recent clinical practice guidelines from the North American and European Societies for Pediatric Gastroenterology, Hepatology, and Nutrition state that the UGI is not useful for diagnosing GER but can help exclude or confirm anatomic abnormalities that cause symptoms similar to GER. The brief duration of the UGI series results in false-negative results, whereas the frequent occurrence of nonpathological reflux results in false-positive results. Thus, the UGI series is not a useful test to reliably determine the presence or absence of GER. In patients with severe and/or complicated GERD who will be managed with gastrostomy tube placement and Nissen fundoplication or with gastrojejunostomy tube, the UGI is useful to exclude anatomic abnormalities such as esophageal stricture or malrotation that would need to be addressed at the time of surgery.

Reflux Scintigraphy

Reflux scintigraphy with technetium-99 metastable (Tc-99m)-labeled sulfur colloid mixed in a feeding was noted by one author to be 79% sensitive when compared to a 24-hour pH esophageal probe as a standard. Nuclear medicine scintigraphy can be used over a prolonged time without increasing radiation exposure and at a lesser radiation dose than the UGI series. Methodology and interpretation criteria are not uniform from center to center. Several studies have tried to standardize the methodology of the examination. A 1-hour scintigraphic study formatted in 60-second frames provides a quantitative representation of postprandial GER for children, particularly if they do not have rapid gastric emptying. False-negative examinations can be associated with delayed gastric emptying, and in this patient group prolongation of the study beyond 60 minutes or confirmatory pH probe evaluation may be advisable. One author proposes that placing the patient in multiple positions during the scan results in a percentage yield of a positive study that is three-fold that of the conventional supine position technique.

In a series of symptomatic and asymptomatic preterm infants who had reached 32 to 34 weeks postconceptional age, radionuclide scintigraphy demonstrated a high incidence of reflux in both groups that did not correlate with symptoms. Use of this study thus may be limited to patients older than 3 months of age in which other modalities have excluded an anatomic cause for feeding disorders.

Ultrasound

There is limited experience with the use of US for diagnosis of reflux, and inconsistent results are reported with sensitivity ranging from 38% to 100%. US diagnosis of reflux is made by noting water placed into the stomach refluxing into the distal esophagus (after tube removal). However, there is no standardization of the study and the amount of water and duration of observation varies.

Evaluation for Delayed Gastric Emptying and Pylorospasm

UGI series, as well as US and scintigraphy, can show gastric emptying that, when delayed, may indicate pylorospasm as a cause of persistent vomiting. The UGI series is helpful in diagnosing HPS, hiatal hernia, GER, and duodenal abnormalities that result in delayed gastric emptying.

Delayed images in standard positions allow scintigraphy to assess gastric transit without additional radiation exposure. Delayed gastric emptying has been defined as more than 50% retained labeled liquid within the stomach after 120 minutes in children younger than 2 years of age.

There is limited information about US imaging of pylorospasm and delayed gastric emptying. Postprandial evacuation of the stomach in infants has been described using functional US by monitoring antral areas. US allows evaluation of normal and abnormal pyloric lengths and muscle wall thicknesses. Antropyloric muscle wall thickness measurements are normally 1 mm to 2 mm. In patients with pylorospasm the muscle thickness can occasionally be in the range of 2 mm to <3 mm. Some of these patients may evolve to pyloric stenosis. One study showed that compared to patients with pyloric stenosis, in pylorospasm the muscle thickness and length vary during the study. In 18 of 31 patients with pylorospasm a transient pyloric muscle wall thickness >4 mm was measured, and 6 patients had pyloric length of >18 mm, simulating HPS for at least a portion of their US study. Changeability of these measurements and evident gastric emptying of inserted fluid helped confirm the US diagnosis of pylorospasm.

Other Conditions

Gastric ulcers are now typically diagnosed by endoscopy.

Chronic gastric volvulus is another rare consideration. In the neonatal and infant group, its primary presentation is recurrent vomiting. Though radiographs show no characteristic finding, the UGI series may show a high greater curvature, a greater curvature crossing the esophagus, a downward-pointing pylorus, two air-fluid levels, or a lowering of the gastric fundus, all of which are suggestive of gastric torsion. Gastric volvulus should be considered in infants presenting with sudden episodes of cyanosis and apnea, anorexia, or pneumonia in association with recurrent vomiting.

Variant 4: New Onset Nonbilious Vomiting

The most common conditions to produce acute nonbilious vomiting during infancy are GER, viral gastroenteritis, pylorospasm, and HPS.

HPS is typically suggested by forceful bile-free emesis in a previously healthy infant around 6 weeks of age. Forceful vomiting may be reported in patients with GER, particularly in overfed patients.

When a classic "olive" of hypertrophied pyloric muscle is palpated, the diagnosis of HPS can be made clinically, and the patient can be sent to surgery for a pyloromyotomy, without the need for imaging examinations. Recent advances in laparoscopic surgery suggest that accurate measurements of pyloric muscle thickening are useful in the planning of surgery, even when the diagnosis is clinically evident. When no "olive" is palpated, imaging by US or a UGI series can be performed for diagnosis.

Evaluation for Hypertrophic Pyloric Stenosis

Radiographs

Abdominal radiography may show gastric distension with HPS. On occasion, mass impression of the thickened pyloric muscle on an air-filled gastric antrum may be noted. However, radiographs are most often not helpful in HPS diagnosis and are usually nonspecific in cases of GER or gastroenteritis.

Upper Gastrointestinal Series

Though the contrast UGI series is excellent for diagnosing obstructive causes of vomiting in this age group, it has the limitation of using ionizing radiation and therefore is less ideal than US as an initial screening test if HPS is a strong consideration.

When doing a UGI in cases of HPS one can note the mass impression of the hypertrophied pyloric muscle on the barium-filled antrum ("shoulder sign") or the filling of the proximal pylorus ("beak sign") or the entire elongated pylorus ("string sign") with barium. The UGI series allows diagnosis of GER as well as less common causes of obstruction such as midgut volvulus, gastric volvulus, or annular pancreas. Because of the delayed gastric emptying present in cases of HPS the demonstration of the beak and string signs can be difficult to identify, often requiring considerable fluoroscopic time with a resultant increase in radiation exposure.

Ultrasonography

US has become a standard and highly accurate method for diagnosing HPS without the need for radiation exposure. It allows real-time imaging of the pyloric muscle and channel. The diagnosis of HPS is based on imaging of a constant elongated, thick-walled pylorus with no passage of gastric content. The diagnosis is supported by measurements of pyloric channel length and muscle thickness. Muscle thickness of ≥4 mm with a length of >18 mm are considered positive for HPS, but measurements between 3 and 4 mm may also be positive, particularly in the premature or younger neonate. Muscle thickness measurement may be obtained on transverse or longitudinal views of the pylorus.

In few patients there is overlap of these measurements, most notably between patients with pylorospasm and patients with evolving HPS. Diagnostic caution with careful clinical follow-up has been suggested for the diagnosis of pylorospasm to avoid the possibility of underdiagnosing cases evolving into HPS. Pylorospasm is said to be the most common cause of gastric outlet obstruction in this age group and, unlike HPS, it is treated conservatively.

Nuclear Scintigraphy

Nuclear scintigraphy has little place in the evaluation of the 6-week-old infant with projectile vomiting. If all other causes of vomiting have been excluded, it may be useful for functional evaluation of gastric emptying, although such patients are typically older than 3 months of age by the time scintigraphy is requested.

Ultrasound versus Upper GI for HPS

US has the advantage over UGI series in that it does not use ionizing radiation. However, a negative US does not exclude other pathologies, and some patients will need further evaluation with a UGI study, which can lead to increased imaging expense. One study, in reviewing the cost, risk and benefit of first using US in the analysis of the vomiting child in two pediatric hospitals, found a 33% reduction in the number of UGI series performed, but a 95% increase in overall cost because the remaining patients went on to a UGI series. Another study found an increased cost among their patients because only 44% had HPS and the others went on to a UGI series.

Cost analyses that support UGI as the initial imaging study in patients suspected of having HPS may not be generalizable, because the percentage of infants with projectile vomiting who have a US examination and then go on to a UGI series varies greatly with the clinical and US practice of a given institution.

US is the first study of choice when there is a strong clinical suspicion of HPS. UGI series is an appropriate first study in infants with an atypical presentation for HPS or when the exam will be performed at a center with limited experience with US evaluation of the pylorus.

Summary of Recommendations

- In imaging a child with bilious vomiting with possible malrotation, a UGI series should be the examination of choice.
- In children with bilious vomiting, if an abdominal radiograph suggests a distal obstruction, then a water-soluble contrast enema should be considered.
- The imaging evaluation of intermittent vomiting in infants depends on the clinical scenario, and imaging is not always necessary. UGI is the preferred imaging when anatomy evaluation is indicated. Radionuclide scans can also play a role in assessing the severity of GER and gastric emptying.
- In imaging an infant younger than 3 months with projectile vomiting, US should be the first imaging consideration for diagnosis of HPS. UGI should be considered if the technician has limited experience with US and when clinical presentation is atypical for HPS.

Abbreviations

- GER, gastroesophageal reflux
- GI, gastrointestinal
- Tc-99m, technetium-99 metastable
- UGI, upper gastrointestinal
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Vomiting in the first 3 months of life

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Emergency Medicine

Family Practice

Gastroenterology

Nuclear Medicine

Pediatrics

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of various imaging modalities in the initial examination of infants with vomiting in the first 3 months of life

Target Population

Newborns and infants up to 3 months of age with vomiting

Interventions and Practices Considered

1. X-ray
    - Upper gastrointestinal (UGI) series
    - Abdomen
    - Contrast enema
2. Ultrasound (US), abdomen (UGI tract)
3. Technetium-99 metastable (Tc-99m) sulfur colloid reflux scintigraphy

Major Outcomes Considered

- Utility of radiologic examinations in differential diagnosis
- Sensitivity, specificity, and positive predictive values of radiologic examinations
- False-positive and false-negative rates

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Of the 58 citations in the original bibliography, 36 were retained in the final document. Articles were removed from the original bibliography if they were more than 10 years old and did not contribute to the evidence or they were no longer cited in the revised narrative text.

A new literature search was conducted in July 2013 to identify additional evidence published since the *ACR Appropriateness Criteria® Vomiting in Infants Up to 3 Months of Age* topic was finalized. Using the search strategy described above, 24 articles were found. Two articles were added to the bibliography. Twenty-two articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, the results were unclear, misinterpreted, or biased, or the articles were already cited in the original bibliography.

The author added 5 citations from bibliographies, Web sites, or books that were not found in the new literature search.

Number of Source Documents

Of the 58 citations in the original bibliography, 36 were retained in the final document. The new literature search conducted in July 2013 identified two articles that were added to the bibliography. The author added 5 citations from bibliographies, Web sites, or books that were not found in the new literature search.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
c. The study is an expert opinion or consensus document.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development documents (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The American College of Radiology (ACR) Appropriateness Criteria (AC) methodology is based on the RAND Appropriateness Method. The appropriateness ratings for each of the procedures or treatments included in the AC topics are determined using a modified Delphi method. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. The expert panel members review the evidence presented and assess the risks or harms of doing the procedure balanced with the benefits of performing the procedure. The direct or indirect costs of a procedure are not considered as a risk or harm when determining appropriateness. When the evidence for a specific topic and variant is uncertain or incomplete, expert opinion may supplement the available evidence or may be the sole source for assessing the appropriateness.

The appropriateness is represented on an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate" where the harms of doing the procedure outweigh the benefits; and 7, 8, or 9 are in the category "usually appropriate" where the benefits of doing a procedure outweigh the harms or risks. The middle category, designated "may be appropriate", is represented by 4, 5, or 6 on the scale. The middle category is when the risks and benefits are equivocal or unclear, the dispersion of the individual ratings from the group median rating is too large (i.e., disagreement), the evidence is contradictory or unclear, or there are special circumstances or subpopulations which could influence the risks or benefits that are embedded in the variant.

The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating. To determine the panel's recommendation, the rating category that contains the median group rating without disagreement is selected. This may be determined after either the first or second rating round. If there is disagreement after the second rating round, the recommendation is "May be appropriate."

This modified Delphi method enables each panelist to articulate his or her individual interpretations of the evidence or expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. For additional information on the ratings process see the Rating Round Information document on the ACR Web site.

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

One study, in reviewing the cost, risk and benefit of first using ultrasound (US) in the analysis of the vomiting child in two pediatric hospitals, found a 33% reduction in the number of upper gastrointestinal (UGI) series performed, but a 95% increase in overall cost because the remaining patients

went on to a UGI series. Another study found an increased cost among their patients because only 44% had hypertrophic pyloric stenosis (HPS) and the others went on to UGI series.

Cost analyses that support UGI as the initial imaging study in patients suspected of having HPS may not be generalizable, because the percentage of infants with projectile vomiting who have a US examination and then go on to a UGI series varies greatly with the clinical and US practice of a given institution.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Summary of Evidence

Of the 43 references cited in the *ACR Appropriateness Criteria® Vomiting in Infants up to 3 Months of Age* document, all of them are categorized as diagnostic references including 1 well-designed study, 4 good quality studies, and 14 quality studies that may have design limitations. There are 24 references that may not be useful as primary evidence.

While there are references that report on studies with design limitations, 5 well-designed or good quality studies provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of newborns and infants with vomiting

Potential Harms

- Though the contrast upper gastrointestinal (UGI) series is excellent for diagnosing obstructive causes of vomiting in this age group it has the limitation of using ionizing radiation and therefore is less ideal than ultrasound (US) as an initial screening test if hypertrophic pyloric stenosis (HPS) is a strong consideration.
- Ultrasound, UGI series, X-ray contrast enema, and reflux scintigraphy with technetium-99 metastable (Tc-99m)-labeled sulfur colloid can render false-positive and false-negative results.

Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional

information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Raske ME, Dempsey ME, Dillman JR, Dory CE, Garber M, Hayes LL, Iyer RS, Kulkarni AV, Myseros JS, Rice HE, Rigsby CK, Ryan ME, Strouse PJ, Westra SJ, Wootton-Gorges SL, Coley BD, Karmazyn B, Expert Panel on Pediatric Imaging. ACR Appropriateness CriteriaÂ® vomiting in infants up to 3 months of age [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 10 p. [43 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1995 (revised 2014)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Pediatric Imaging

Composition of Group That Authored the Guideline

Panel Members: Molly E. Raske, MD (*Principal Author*); Molly E. Dempsey, MD; Jonathan R. Dillman, MD; Christopher E. Dory, MD; Matthew Garber, MD; Laura L. Hayes, MD; Ramesh S. Iyer, MD; Abhaya V. Kulkarni, MD; John S. Myseros, MD; Henry E. Rice, MD; Cynthia K. Rigsby, MD; Maura E. Ryan, MD; Peter J. Strouse, MD; Sjirk J. Westra, MD; Sandra L. Wootton-Gorges, MD; Brian D. Coley, MD (*Specialty Chair*); Boaz Karmazyn, MD (*Panel Chair*)

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Bulas D, McGrane SL, Coley BD, Karmazyn B, Barr LL, Binkovitz LA, Dory CE, Garber M, Hayes LL, Keller MS, Kulkarni AV, Meyer JS, Milla SS, Myseros JS, Paidas C, Expert Panel on Pediatric Imaging. ACR Appropriateness Criteria® vomiting in infants up to 3 months of age. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 9 p. [58 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available

from the American College of Radiology (ACR) Web site.

- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Electronic copies: Available from the ACR Web site.
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the ACR Web site.
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available from the ACR Web site.
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2015 Feb; 2 p. Electronic copies: Available from the ACR Web site.
- ACR Appropriateness Criteria® vomiting in infants up to 3 months of age. Evidence table. Reston (VA): American College of Radiology; 2014. 13 p. Electronic copies: Available from the ACR Web site.
- ACR Appropriateness Criteria® vomiting in infants up to 3 months of age. Literature search. Reston (VA): American College of Radiology; 2014. 1 p. Electronic copies: Available from the ACR Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on March 30, 2006. This summary was updated by ECRI Institute on July 22, 2009 and July 7, 2011. This summary was updated by ECRI Institute on April 16, 2015.

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